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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/563,747	Applicant(s) HARREN ET AL.	
	Examiner Nissa M. Westerberg	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22 - 69 is/are pending in the application.
- 4a) Of the above claim(s) 48, 49, 63 - 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22 - 47, 50 - 62 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/16/16, 5/9/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I (claims 22 – 47, 50 – 62 and 69) with the presence of a film layer in the reply filed on April 2, 2008 is acknowledged. The election of a specific material for the film layer was not required.

The requirement is still deemed proper and is therefore made FINAL.

Comments and Notes

Various claims of the instant application (for example, claims 23 – 27) contain lists of items from which at least one item must be selected. These claims do not use the standard Markush group language of "selected from the group consisting of A, B and C." While the claims which contain these lists are not rendered vague and indefinite by the use of non-standard language, it is kindly suggested that Applicant use the standard Markush format to present the claims in a clearer format.

Claim 69 of the instant application, a use claim, has been interpreted as a composition claim with the claimed components in a product that is either a hygiene article or a wound treatment article. If this is not what Applicant intended to claim in this

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Applicant, Applicant is kindly requested to amend the claim to clearly define the subject matter being claimed. If claim 69 is amended, the next action may be made final.

Claim Objections

2. Claims 22, 31 and 69 are objected to because of the following informalities: each claim is one sentence in length and therefore contains only one period. In each of these claims, the identifiers for the various items in the list also include a period. For example, claim 22 contains "Φ1." And "Φ2." as item identifiers. Appropriate correction is required.

3. Claim 50 is objected to as depending from withdrawn claim. Claim 48 has been withdrawn from consideration as being not drawn to the elected invention. Appropriate correction is required.

4. Claim 50 is also objected to because of the multiple periods which are present in the various item identifiers in claim 48. A proper claim can only contain one period. Appropriate correction is required.

Claim Rejections - 35 USC § 112 1st Paragraph

5. The following is quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 30, 33 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No description of the method used to determine the particle size, centrifuge retention capacity, absorption against pressure, water soluble polymer content and residual moisture is provided in the specification.

Claim Rejections - 35 USC § 112 2nd Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 22 – 30, 45, 35, 38, 40, 22, 44, 50, 51, 56 and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims contain the limitation “less than about” (“under about” in claim 29, “at most about” in claims 33 A5) and 51 A5), to which similar logic applies). “Less than”, “under” and “at most” each indicate a maxima and all possible values below the recited value are encompassed. “About” indicates a range centered on the recited value. Therefore, what values are included in the range “less than about” cannot be determined and the

limitations of the claims cannot be determined. Claim 50 is rejected because of the presence of "less than about" in claim 48, the withdrawn claim from which claim 50 depends.

9. Claims 28 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "substantially" is a relative term which renders the claim indefinite. The terms "substantially homogenous" in claim 28 and "amounts substantially to about 100%" in claim 34 are not defined by the claim or the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

10. Claims 30, 33 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite properties of the material that must be determined by a specific test, such as ERT 420.1-99 and ERT 441.1-99. The abbreviation ERT is defined on p 37, but what steps the various test procedures entail to determine the various claimed parameters are not described in the specification. As the methods by which these properties are determined is essential for determining whether or not a composition falls within the scope of the claims, the metes and bounds of these claims can not be determined. For example, it is unclear whether the particle size determined by ERT 420.1-99 is a number or sized weight average

diameter and what all is determined in this test, as ERT 410.1-99 is also disclosed as determining the residual monomer content (p 5, ln 16 – 17 of the instant specification).

11. Claims 46, 47 and 60 – 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In these claims, a composition or composite further comprises a hygiene article. It is unclear how the “smaller” component can further comprise the “larger” component. For example, one would not claim “an engine according to claim 1 that further comprises a car” but would rather claim “a car according to claim 1 which further comprises an engine.”

12. Claim 69 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim provides for the use of active substance-doped, water absorbing polymer particles or a water-absorbing composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

13. 35 U.S.C. § 101 reads as follows:

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"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

14. Claim 69 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 22 – 25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Ueda et al. (PGPub 2003/0004479).

Ueda et al. disclose a particulate water-absorbing composition and structures comprising the particulate in such products as disposable diapers, sanitary napkins and incontinent pads with excellent deodorizability and absorption properties (paragraph [0001]). These particulates comprise a plant powder (active substance) and a water adsorbent material (paragraph [0015]) wherein the plant powder is present in an amount

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of 0.001 to 20 weight parts per 100 weight parts of the solid content of the water absorbent material (paragraph [0017]). Examples of water-absorbent materials include partially neutralized and crosslinked polyacrylic acid (paragraph [0033]) wherein the neutralization of the acid group is in the range of 30 to 100 mol % (paragraph [0036]). 0.01 to 2 mol% of a crosslinking agent may be present to cross link the water-absorbent material (paragraphs [0039], [0041]). The plant powder active material may be a variety of ingredients (paragraphs [0073] – [0076]) and acts as a deodorizer. In Table 1 (p 25), materials are made in which a variety of plant powders (such as pepper, citron, lime peel, Mandarin orange peel, tea extract and capsicum) are prepared with water-absorbent resins 1 or 2. These resin materials are prepared in referential examples 1 and 2 (paragraphs [0224] – [0227]) and contain sodium acrylate with a neutralization ratio of either 75 mol % or 38 mol%. The weight average particle diameters of the resin particles were 295 µm and 360 µm respectively. As the same composition as claimed is present, the composition appears to inherent meet the limitation for the residual monomer content of under about 500 ppm.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 22, 45 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al.

As discussed above, Ueda et al. discloses particulate water-absorbing compositions comprising deodorizing plant powders with a partially neutralized (38 mol% or 75 mol%) sodium acrylate composition. The particles can be used as water-

absorbing portion in hygiene products such as disposable diapers, sanitary napkins and incontinence pads (paragraph [0001]).

Ueda et al. does not explicitly disclose a composition with multiple ingredients to obtain a composite or a hygiene article.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a composite hygiene article with the acrylate water-absorbing polymers exemplified by Ueda et al. as Ueda et al. clearly discloses that these polymers are suitable for use in such products.

21. Claims 22, 45 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. in view of Chmelir et al. (US 6,552,141).

As discussed above, Ueda et al. discloses particulate water-absorbing compositions comprising deodorizing plant powders with a partially neutralized (38 mol% or 75 mol%) sodium acrylate composition. The particles can be used as water-absorbing portion in hygiene products such as disposable diapers, sanitary napkins and incontinence pads (paragraph [0001]).

Ueda et al. does not explicitly disclose a residual monomer content of under about 500 ppm.

Chmelir et al. discloses a process for making polymers acrylic acid or derivatives of acrylic acid that have a high absorptive capacity for water, aqueous solutions and body fluids (col 1, 5 – 10). The monomers of the polymer product are known to be toxic (col 1, ln 32 – 34) is desirable.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a particulate-water absorbing composition as taught by Ueda et al. and to minimize the amount of residual monomer content in the final polymer, as that monomer is known to be toxicity, as stated by Chmelir et al.

22. Claims 22 – 34, 37, 39, 40, 43 – 47, 50 – 52, 55, 60 – 62 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Champ et al. (DE 10257002; the Derwent abstract and machine translation of the entire document are included with this Office Action) in view of Ueda et al. (PGPub 2003/0004479).

Champ et al. discloses open-cell hydrogel foam based on crosslinked acid-functional polymers including skin care agents (“novelty”, p 1 of Derwent abstract). These materials that can be used in the sanitary articles will have a positive influence on the skin of the user (paragraph 5, p 1, machine translation). The material contains 10 - 80 weight percent of partially neutralized acid group containing ethylenically unsaturated monomers, optional another such monomer and 0.001 – 5 weight percent cross lining agent (Vernetzer; paragraph 10, p 1, machine translation). Examples of the acid groups include acrylic acid and methacrylic acid (paragraph 2, p 2, machine translation). Among the skin care products that may be added as are panthenol, collagen, vitamin A, vitamin E (paragraph 2, p 4, machine translation), a variety of perfumes (paragraph 5, p 4, machine translation) and *Aloe barbadensis* (see example 1(B), p 6 of machine translation). *Aloe barbadensis* is also a wound-treatment substance (p 9, ln 17 – 18 of the instant specification). The portion of the skin care

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product in the solution can range from 1 to 50 weight percent (paragraph 1, p 5, machine translation). In examples 1 – 3, 10% aloe, 5% vitamin A or vitamin E were added to the partially neutralized acrylic acid foam material (p 6 of machine translation). After drying overnight, the foams with the active ingredient were placed in a sanitary article (Example 1(B)) and were able to constantly release the skin care active ingredient to the skin (examples 2 and 3). The preferred water content of the foamed material is preferably between 5 and 60 weight percent (paragraph 4, p 2, machine translation).

The preferred structure of the sanitary article has an absorbent core fixed between and topsheet and backsheet (paragraph 2, p 5, machine translation). The topsheet may be made of polyester (a polycondensate film layer; paragraph 3, p 5, machine translation), and a backsheet film layer, both of which are adjacent to water-absorbing polymer composition. Given the stated constant release of the active material from the composition, whose ingredients are the same as those used by Applicant, it appears that properties of the composition (for example, particle size, active substance availability and residual moisture) are inherently present in the composition/composite/hygiene article. A moisture content of between 1 and 80 weight percent or between 5 and 60 weight percent for the water-absorbing polymer is disclosed (paragraph 4, p 2, machine translation). The amount of water influences the flexibility of the materials (paragraph 4, p 2, machine translation).

Champ et al. does not disclose the use of polymer particles, but rather uses an open cell foam, and Champ et al. does not explicitly disclose a residual moisture content of at most about 15 weight percent.

Ueda et al. discloses a particulate formulations of a partially neutralized and crosslinked polyacrylic acid (paragraphs [0001] and [0033]) that can be used as the water-absorbing portion of hygiene products such as disposable diapers, sanitary napkins and incontinence pads (paragraph [0001]). The particles prepared in referential examples 1 and 2 (paragraphs [0224] – [0227]) contain sodium acrylate with a neutralization ratio of either 75 mol % or 38 mol% and the resulting particles have a weight average particle diameters of the resin particles were 295 μm and 360 μm respectively.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare an absorbent polymer and sanitary article or other hygiene product as taught by Champ et al. and to make the water-absorbing polymer in the form of particles, taught by Ueda et al. as a suitable configuration for the water-absorbing portion of hygiene articles using the same water-absorbing polymers. It also would have been obvious to prepare the water-absorbing polymer with a residual moisture content in the water-absorbing polymer of at most about 15 weight percent as the range taught by the prior art and the range claimed by Applicant are overlapping and this one parameter which can be adjusted to alter the flexibility of the resulting product.

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23. Claims 31, 35, 37 – 42, 50, 53, and 55 – 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Champ et al. and Ueda et al. as applied to claims 22 – 34, 37, 39, 40, 43 – 47, 50 – 52, 55, 60 – 62 and 69 above, and further in view of Morman et al. (US 5,883,028).

As discussed above, Champ et al. and Ueda et al. disclose various hygiene products that comprise a foam or particle water-absorbing component in which an active ingredients, such as a deodorizing plant powder, aloe, vitamin A, vitamin E or other skin care active ingredients are present. To form the composite hygiene article, a topsheet and a backsheet film layer are added.

Neither reference discloses the use of polyurethane in these layers or physical properties such as the water vapor permeability of the film layer.

Morman et al. discloses a breathable elastic laminate particularly useful as an outer cover for disposable diapers and other personal care disposable products (col 1, ln 5 – 10). Good water vapor transmission makes the products more comfortable for the wearer (col 26 – 32). Suitable polycondensate polymer materials include polyurethanes (col 2, ln 1 – 5; example 3, col 13) and polyether esters (col 2, ln 1 – 5, example 2, col 13). The moisture vapor transmission rate (water vapor permeability) of the polymer layer should be at least $300 \text{ g/m}^2\text{-24 hours}$ (col 6, ln 13 – 18). The polymer films described by Morman et al. are highly permeable water but have a low permeability to ammonia and other odor-causing materials (col 1, ln 51 – 52), to allow for comfort while wearing by allowing for transmission of water vapor while reducing odors associated with ammonia in urine and other odor-causing substances.

It would have been obvious to one of ordinary skill in the art at the time of the instant to use the polyurethane films, taught by Morman et al. as increasing comfort and decreasing ammonia odor in diapers and other disposable personal care articles, as the film material on the personal hygiene products or composites to provide the hygiene articles taught by Champ et al. and Ueda et al. with improved wearability and decreased odor.

24. Claims 31, 36, 50 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Champ et al. and Ueda et al. as applied to claims 22 – 34, 37, 39, 40, 43 – 47, 50 – 52, 55, 60 – 62 and 69 above, and further in view of Kenndoff et al. (US 5,844,013).

As discussed above, Champ et al. and Ueda et al. disclose various hygiene products that comprise a foam or particle water-absorbing component in which an active ingredients, such as a deodorizing plant powder, aloe, vitamin A, vitamin E or other skin care active ingredients are present. To form the composite hygiene article, a topsheet and a backsheet film layer are added.

Neither reference discloses the use of a foam polycondensate material.

Kenndoff et al. discloses hydrophilic polyurethane gel foams for use in products such as wound dressings that absorb and bind aqueous liquids (col 1, ln 8 – 10, 19 – 20). These materials may also serve a matrix for active substances (col 1, ln 33 – 37). The hydrogels of Kenndoff et al. contain less absorber material, do not in principle require an additional-antistick layer and the foams will adhere to the skin but will not

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adhere to the wound surface (col 2, ln 31 – 35). These foams can be made by the combination of polyhydroxyl compound and polyisocyanate (which, when polymerized, result in polyurethane), a superabsorber and an accelerator (col 8, ln 10 – 30).

Preferred materials are water-absorbing salts, known as superabsorbers, of polyacrylates and copolymers thereof, particularly the sodium or potassium salts (col 7, ln 21 – 29). The water-absorbing superabsorber compound is preferably present in finely ground form, particularly when thin foam layers are required (col 7, ln 46 – 54). The hydrogel foam can be applied to sheet like backing materials, such as polyurethane sheets (col 6 – 24).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a foam layer wherein a polyacrylate water absorbing material is present in a polyurethane foam, as taught by Kenndoff et al. to decrease the amount of absorber needed and allowing for greater flexibility in the absorption behavior of the material, and to use the partially neutralized polyacrylate water-absorbing polymer with active ingredients, taught by Champ et al. and Ueda et al., to deliver the deodorizing, skin care or wound healing active ingredient using the bandage or other hygiene product.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is

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(571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW